

REMARKS

The claims pending in the Application after entry of the present Amendment will be claims 1-42 and 45-47. Claims 1, 11, and 41 have been amended to delete “hydrogen” from the definition for variable “R₆”. Claim 1 has also been amended to import the phrase “wherein a dosage of a compound of Formula I is between”. Support for this amendment is found, for example, at pages 133-134, paragraph [0308]. Additionally, Claim 1 has been amended to import the phrase and “for treating tumor metastases.” Support for this amendment is found, for example, at page 119, paragraph [0247], page 121, paragraph [0254], page 124, paragraph [0263] and page 125, paragraph [0269], etc. No new matter has been added by these amendments. Applicant reserves the right to pursue any canceled subject matter in future applications that claim priority to the present application. None of the above amendments add new matter to the claims.

I. Discussion of Election/Restriction

The Office Action (page 2, point 1) indicates that claims 13, 15, 21-26, 28-29, and 31-40 “[...] are withdrawn because they do not read on the elected species.” However, Applicant respectfully observes that two rejections levied under 35 U.S.C. §112, second paragraph in the instant Office Action are directed to claims 1-42 and claims 45-47. Claims 1-42 and 45-47 contain both “elected” and “non-elected” claims. Thus, Applicant was not certain whether claims 13, 15, 21-26, 28-29, and 31-40 had been rejoined. Applicant requested clarification of same via a phone call to Examiner Havlin on October 13, 2009, where he clarified that the two rejections levied under 35 U.S.C. §112, second paragraph, were intended only for the claims that were not withdrawn (i.e., for claims 1-12, 14, 16-20, 27, 30, 41-42 and 45-47). Taking this clarification into consideration, Applicant now addresses the two rejections levied under 35 U.S.C. §112, second paragraph, for claims 1-12, 14, 16-20, 27, 30, 41-42 and 45-47 only, not the claim numbers set forth by the Examiner in the Office Action.

Should the Examiner deem that there is allowable subject matter in the present claims as amended, Applicant respectfully requests that the Examiner consider the following comments. MPEP §821.04 states:

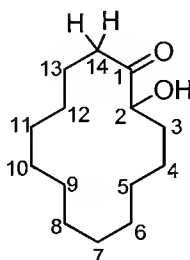
“The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.”

Applicant submits that because claim 1 (i.e., the elected invention) as amended is now in condition for allowance, all dependent claims therefrom are also patentable and allowable. Applicant respectfully requests that the claims deemed “non-elected” (i.e., claims 13, 15, 21-26, 28-29, and 31-40) are now appropriate subject matter for rejoinder. Therefore, Applicant respectfully requests that examination on the merits proceed accordingly, i.e., if there is no art that anticipates or renders obvious the elected species, then Applicant requests that the search of the claim be extended.

To facilitate prosecution, Applicant has utilized the claim identifiers, “Original”, “Previously Presented”, “Currently Amended”, “Withdrawn/Original” and “Withdrawn/Previously Presented”, in the section entitled “Amendments to the Claims.”

II. Rejection under 35 U.S.C. §102(b)

Claims 1, 11, 16 and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Singh et al. [Indian Journal of Chemistry, Section B: Organic Chemistry Including Medicinal Chemistry (2002), 41B(2), 423-426]. Specifically, the compound of Singh et al. has the following structure:



2-hydroxycyclotetradecanone,

and corresponds to Applicant’s claimed compound wherein each of R_a , R_b , R_1 , R_2 , R_3 , Y_1 , Y_2 , R^{X1} , and R^{X2} , are defined as hydrogen; and R_4 is defined as “oxo”. Applicant has amended

claims 1, 11, and 41 to eliminate the possibility that R_6 = hydrogen, i.e., R_6 now requires something other than hydrogen. Applicant respectfully submits that the above amendment renders the rejection under 35 U.S.C. §102(b) moot.

III. **Rejection under 35 U.S.C. §112, para. 2**

Claims 1-42 and 45-47 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner asserts that the following language does not make clear which component of the composition is relative to body weight.

“ . . .whereby the composition is formulated for administration to a subject at a dosage between about 0.1 mg/kg to about 50 mg/kg of body weight. . .”

For example, the Examiner inquires whether it is the total mass of the composition or only the mass of the active ingredient that is relative to the body weight. Applicant has amended claim 1 to import the phrase “wherein a dosage of a compound of Formula I is between.” Applicant respectfully submits that the above amendment renders the rejection under 35 U.S.C. §112, paragraph 2 moot.

IV. **Rejection under 35 U.S.C. §112, para. 2**

Claims 1-42 and 45-47 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner asserts that one of ordinary skill in the art would not know what the phrase “therapeutically effective amount” is without any reference to a therapy, because a therapy has not been defined and it is not clear to which therapy Applicant refers. Applicant has amended claim 1 to insert the phrase “for treating tumor metastases.” Applicant respectfully submits that the above amendment renders the rejection under 35 U.S.C. §112, paragraph 2 moot.

V. **Supplemental IDS and SB/08 Form**

In order for the file history to reflect that the Examiner has examined the instant application with respect to every reference, Applicant submits concurrently herewith a Supplemental Information Disclosure Statement and accompanying Form SB/08. **All references cited herein are references taken directly from the specification as filed.** Applicant respectfully requests that these references be considered and acknowledged; and further respectfully requests that the Examiner place initials after each, to indicate that appropriate consideration of them was made during examination.

In light of the above Remarks and Amendments, Applicants invite the Examiner to contact the undersigned, Julie Anne Knight, at (617) 248-5227, with any questions pertaining to the above-identified application in order to expedite prosecution of this case.

Respectfully submitted,

Dated: October 21, 2009

/Julie Anne Knight/

Julie Anne Knight

Reg. No. 48,867

PATENT GROUP
CHOATE, HALL & STEWART
Two International Place
Boston, MA 02110
Tel: (617) 248-5227
Fax: (617) 502-5002
jknight@choate.com